§ 7.22b Petitions for exemption from major food allergen labeling.

(a) Submission of petition. Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of §7.22a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in §7.22(a)(1)(i), even though a major food allergen was used in production.

(b) Decision on petition. TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of a petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) Resubmission of a petition. After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition.

(d) Availability of information—(1) General. TTB will promptly post to its public Web site, http://www.ttb.gov, all petitions received under this section as
well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5 U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) Requests for confidential treatment of business information. A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

[T.D. TTB–53, 71 FR 42269, July 26, 2006]

§7.24 Class and type.

(a) The class of the malt beverage shall be stated and, if desired, the type thereof may be stated. Statements of class and type shall conform to the designation of the product as known to the trade. If the product is not known to the trade under a particular designation, a distinctive or fanciful name, together with an adequate and truthful statement of the composition of the product, shall be stated, and such statement shall be deemed to be a statement of class and type for the purposes of this part.

(b) Malt beverages which have been concentrated by the removal of water therefrom and reconstituted by the addition of water and carbon dioxide shall for the purpose of this part be labeled in the same manner as malt beverages which have not been concentrated and reconstituted, except that there shall appear in direct conjunction with, and as a part of, the class designation the statement “PRODUCED FROM CONCENTRATE” (the blank to be filled in